ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

I.B.1.1. Official name:

Antinal, capsule.

I.B.1.2. Qualitative and quantitative composition of the drug, INN or international non-proprietary name, and name of the active substances:

Each capsule contains:

Substance / active / active substances (*):

Name	Quantity	Unit	Reference / international monographic standard
Nifuroxazide	200	mg	BP 2010

Excipient / excipients (*):

Nom	Quantité	Unité	Reference / international monographic standard
Magnesium stearate	5	mg	BP 2010
Croscaramellose sodium	2	mg	Sp. included
Sucrose	72	mg	BP 2010
Corn strach	84,8	mg	BP 2010

I.B.1.3. Form (including method of administration):

Capsule, per os.

I.B.1.4. Clinical data

4.1 Therapeutic indications:
Acute diarrhea suspected of bacterial origin in the absence of suspicion of invasive phenomena (deterioration of the general state, fever, toxi-infectious signs ...).
The treatment does not dispense dietary measures and rehydration if it is necessary.
The importance of rehydration by oral or intravenous rehydration solution should be adapted according to the intensity of the diarrhea, the age and the peculiarities of the patient (associated diseases, ...).

4.2 Doses and method of administration for adults, and when applicable, for children and / or elderly patients:
This product should be used only in adults and adolescents over the age of 15 years.

This product is administered orally.

Adults: 1 capsule 4 times daily. Capsules should be swallowed whole with water. The treatment should not exceed 3 days.

4.3 Contraindications:

- Hypersensitivity to nitrofuran derivatives or to any of the constituents of the capsule
- Patients under 15 years

4.4 Special warnings and precautions:

Special warnings
If after 2 days of treatment the diarrhea persists, the action to be taken should be re-evaluated and the need for oral or intravenous rehydration should be considered.
In cases of infectious diarrhea with clinical manifestations suggestive of an invasive phenomenon, use antibacterials with good systemic diffusion.
In case of prolonged severe diarrhea, severe vomiting or refusal to eat, intravenous rehydration should be considered.
This medicine contains sucrose. It is not recommended for use in patients with fructose intolerance, glucose-galactose malabsorption or sucrase / isomaltase deficiency.
Precautions for use
The patient should be informed of the need to:
· Rehydrate with abundant, salty or sugary drinks to compensate for fluid loss due to diarrhea (the average daily water intake of adults is 2 liters);
· Feed the time of diarrhea, excluding certain inputs and especially raw vegetables, fruits, green vegetables, spicy dishes, as well as frozen foods or drinks, focusing on grilled meats, rice.

4.5 Drug Interactions, Other Interactions:
This medicine is not compatible with anti-abuse drugs and CNS depressants

4.6 Pregnancy and lactation:

No clinically relevant data are available to evaluate the potential teratogenic or fetotoxic effects of nifuroxazide during pregnancy. Therefore, as a precaution, nifuroxazide should be avoided during pregnancy. Breastfeeding can continue normally if therapy with Antinal is limited in time.

4.7 Effect on ability to drive and drive machines:
No effect on the ability to drive a vehicle.

4.8 Undesirable effects (frequency and seriousness):
Probability of allergic skin reactions such as rash, Quincke edema, urticaria or anaphylactic shock.

4.9 Overdose
No clinical data are available on overdose of nifuroxazide.

I.B.J .5. Pharmacological properties

5.1 Pharmacodynamic properties:
• Pharmacotherapeutic group: other intestinal anti-infective agents: ATC code: A07AX03

5.2 Pharmacokinetic properties

• Absorption of Antinal is extremely low with normal intestinal mucosa

5.3 Preclinical safety data:
no data available

I.B.1.6. Pharmaceutical properties

6.1 List of excipients: Magnesium stearate, Croscaramellose sodium, sucrose, Corn starch

6.2 Major incompatibilities:
no data available

6.3 Time of expiration (finished product, after dilution or reconstitution,
or after opening the package):
3 years

6.4 Special precautions during storage:
store in a dry place at a temperature below 30 ° C.

6.5. Packaging and contents of the packaging:
Box of 24 capsules (2 blisters of 12 capsules).

6.6. Special precautions for disposal and handling
No special requirements.

7. Operator and Manufacturer
HOLDER AND INTERNATIONAL OPERATOR:
FRILAB SA
17 rue des Pierres du Niton
1207 Geneva SWITZERLAND

Manufacturer and holder in the country of origin: AMOUN PHARMACEUTICAL COMPANY

8. DOSIMETRY
Not applicable.

9. INSTRUCTIONS FOR THE PREPARATION OF RADIOPHARMACEUTICALS
Not applicable.